REMARKS

The Specification has been amended to remove browser-executable code, to identify trademarks, and to correct a typographical error.

Claims 8-11 and 13-22 have been canceled. Claims 1, 2, 5, 12 and 23 have been amended. Claims 1-7, 12 and 23-25 are pending.

Claim 1 has been amended to delete the nucleotide sequence which encodes a polypeptide fragment comprising 120 amino acids of 25466 and to clarify the language. Claim 1c) and d) have been amended to add a phrase to recite a function of the encoded polypeptide. Support for this amendment can be found in the Specification, at, for example, paragraph [0038] line 9 and paragraph [00106], line 6. A further amendment to claim 1c) is the recitation of hybridization conditions. Support for this amendment can be found in the Specification, at, for example, paragraph [0068], lines 14-15.

Claim 2 has been amended to clarify the language.

Claims 5 and 23 have been amended to recite "non-human" host cell. Support for the amendment can be found in the Specification at, for example, paragraph [00183], line 3.

Claim 12 has been amended to recite hybridization conditions and variant/domain function and to clarify language, similar to the amendments to claim 1.

The amended claims find support in the application as originally filed. The Amendment does not add new matter. Further remarks are set forth below with reference to the sections of the Office Action.

Objection to the Specification

The specification was objected to because of the presence of browser-executable code. Applicant has amended paragraphs containing this code to cite source information and to disable the code. The Specification was further amended to improve the notification of trademarks in the text. In view of these amendments, Applicant requests that this objection be withdrawn.

Rejection of Claims 5, 6, 23 and 24 Under 35 U.S.C. §101

Claims 5, 6, 23 and 24 were rejected under 35 U.S.C. §101, as being drawn to non-statutory subject matter. The Examiner states that these claims read on cloned humans. In response, Applicant has amended claims 5 and 23 (claims 6 and 24 dependent thereon) to recite "non-human" host cell. In view of these amendments, Applicant asks that this rejection be withdrawn.

Rejection of Claims 1-7, 12 and 23-25 Under 35 U.S.C. §101

Claims 1-7, 12 and 23-25 were rejected under 35 U.S.C. §101, as not being supported by either a specific and substantial asserted utility or a well-established utility. In particular, the Examiner contends that the Uses described in the Specification are only useful in research to determine the function of the encoded protein. The Examiner further contends that the tissue-specific expression such as that found on p. 13 is not specific to the claimed polynucleotide. Applicant respectfully traverses this rejection.

First, Applicant directs the Examiner's attention to the Example, paragraphs [00366] to [00370]. The first two lines of paragraph [00368] note that probes were designed based on the sequence of the 25466 gene. Paragraph [00369] details the method of analysis to determine the expression of 25466. In this paragraph, Applicant has corrected a typographical error to replace non-25466 sequence identifiers with 25466. A person of ordinary skill in the biological arts would recognize the existence of this error as well as the appropriate correction made by the present amendment. Accordingly, this amendment adds no new matter. Together, the statements in this Example make it clear that the tissue-specific expression described on page 13 is specific to the 25466 nucleic acid molecules of the invention.

As for whether this expression described on page 13 indicates a credible, specific, substantial of well-established utility, Applicant points the examiner to the expression noted for tumor samples relative to the corresponding normal tissues. For example, 25466 was found to be expressed at a high level in normal ovary, but only at a trace amount in ovary tumor. Differential 25466 expression also was observed for other tumor tissues (higher expression in tumor, e.g. prostate, breast, colon and lung tumors) compared to corresponding normal tissues. Accordingly, the 25466 molecules of the invention can act as diagnostic agents for cellular proliferative and/or differentiative disorders, as stated in paragraph [0053] of the Specification. "Cellular proliferative and/or differentiative disorders" are defined in paragraph [0056] to include cancer. Cancer is a specific utility, and its connection to 25466 is credible as it arises from actual expression data for 25466. Moreover, it is substantial, as cancer diagnosis has a real world use.

Applicant suggests that this situation is similar to the Caveat accompanying Example 12 of the Utility Guidelines. It appears that Example 12 provides an analysis of asserted utilities for a receptor. In particular, Example 12 rejects a receptor as having an unsubstantial utility due to the receptor being associated with an undisclosed disease or condition. However, the Caveat adjusts the situation by supposing that the receptor is present differentially in a disease condition (melanoma) compared to normal cells. An assumption in this situation is the notion that selective detection of diseased cells is reported to be helpful for diagnosis of the disease. In that Caveat, it is concluded that the receptor then has a "well-established utility" and the utility rejections under 35 U.S.C. §101 and U.S.C. §112, first paragraph, should not be made against the claims.

Applicant submits, in Exhibit A, two journal articles which discuss the usefulness of biomarkers in the diagnosis of ovarian and colon cancers. Applicant has identified 25466 as a monocarboxylate transporter. Two abstracts also submitted with Exhibit A note that the level of gene expression of some transporters, e.g. ABC transporters and a monocarboxylate transporter, can be used as a diagnostic predictor of severity of some cancerous conditions. With these reports of cellular markers, including transporters, as diagnostic indicators of cancers, Applicant asserts that the assumption of the Caveat of Example 12 of the Utility Guidelines is met. The utility of 25466 molecules as diagnostic agents for cellular proliferative and/or differentiative disorders described in the present application is substantial and supported in the literature, so is a well-established utility.

The Examiner further contends that 25466 does not have a well-established utility because recitation of MCT activity is not specific enough. The Examiner believes that the utility of an MCT-like protein could only be possible after knowing the biophysical effects and pharmacological characteristics of the protein; being named a member of the MCT family does not provide utility. However, Applicant believes that the cancer diagnosis utility, discussed above, only requires structural information of the 25466 molecules. Nucleic acid molecules, used as probes, for example, can be used to measure the presence, absence, increase or decrease of 25466 expression within that well-established utility. Applicants note that only one utility is required. In view of these remarks, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. §101 be withdrawn.

Rejection of Claims 1-7, 12 and 23-25 Under 35 U.S.C. §112, First Paragraph

Claims 1-7, 12 and 23-25 were rejected under 35 U.S.C. §112, first paragraph on the grounds that the supposed lack of utility would render the skilled practitioner unable to know how to use the claimed invention. Applicant respectfully traverses this rejection due to the utility described in the section above. Therefore, this rejection should be withdrawn.

Rejection of Claims 1, 3-7, 12, 23 and 24 Under 35 U.S.C. §112, First Paragraph

Claims 1, 3-7, 12, 23 and 24 were rejected under 35 U.S.C. §112, first paragraph because the specification does not reasonably provide enablement for polynucleotides that encode at least 120 contiguous amino acids of SEQ ID NO:2. Applicant has deleted the recitation of the 120 amino acid fragment from claims 1 and 12 (claims 3-7, 23 and 24 dependent thereon). In view of this amendment, Applicant respectfully asks that this rejection be withdrawn.

Claims 1, 3-7, 12, 23 and 24 were further rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the subject matter of

the claims is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner notes that the claims are drawn to a genus including fragments and variants of nucleic acids encoding SEQ ID NO:2, but do not have any functional limitations. Applicant has amended the remaining fragment and variant portions of claims 1 and 12 (claims 3-7, 23 and 24 dependent thereon) to recite the function of binding a monocarboxylated ion. Thus these portions of the claims recite both structure and function. In view of this amendment, Applicant respectfully asks that this rejection be withdrawn.

Rejection of Claims 1, 3-7, 12, 23 and 24 Under 35 U.S.C. §112, Second Paragraph

Claims 1, 3-7, 12, 23 and 24 were rejected under 35 U.S.C. §112, second paragraph on the grounds that the term "stringent conditions" to refer to hybridization to 25466 nucleic acid molecules is a relative term which renders the claims indefinite. Applicant has amended claims 1 and 12 (claims 3-7, 23 and 24 dependent thereon) to recite specific hybridization and wash conditions. In view of this amendment, Applicant respectfully asks that this rejection be withdrawn.

Rejection of Claims 1-7, 12, 23 - 25 Under 35 U.S.C. §102

Claims 1-7, 12 and 23-25 were rejected under 35 U.S.C. §102(a) and (e) as being anticipated by WO 01/60860 (Schlegel et al), in particular the sequence ABV26931, found to be 100% identical to SEQ ID NO:3. Applicant respectfully traverses this rejection.

ABV26931 corresponds to SEQ ID NO:26922 of Schlegel et al.. BLAST analysis also identifies SEQ ID NO:21080 of Schlegel et al. to have this sequence. A ~600 nt version of SEQ ID NO:21080, identified from library cMhqaj, can be found in the WO 01/60860 specification in Table 8, and a 4047 nt version of 21080 which aligns to 25466 can be found in the sequence listing. SEQ ID NO:26922 can be found only in the sequence listing, where it is 322 nt. No description of SEQ ID NO:26922 can be found in the specification; the origin of the version of 26922 which aligns to 25466 is inexplicable. Applicant notes that WO 01/60860 claims priority to six documents, all provisional applications. A survey of those documents finds them to be cumulative, e.g. only two tables are present holding 3662 sequences in the first provisional application (US 60/183,319) and more tables and sequences are added for later provisional applications. Applicant notes that the final provisional application contributing to Schlegel et al. (US 60/255,281) does not contain either SEQ ID NO:26922 nor 21080, nor library cMhqaj. US 60/255,281 has only Tables 1-5 and sequences 1-10246 (see Exhibit B, pages 89-91). Therefore, a resulting conclusion is that Table 8 and sequences beyond 10246 were present only in the US utility application filed on February 16, 2001 and in the PCT application, filed on February 20, 2001. As the present application has a priority date of February 15, 2001, Schlegel et al. does not qualify as 102(a) or

102(e) art for SEQ ID NOs:21080 or 26922 (ABV26931). In view of these remarks, Applicant asks that this rejection be withdrawn.

Claims 1, 3-7, 12 and 23-24 were rejected under 35 U.S.C. §102(a) and (e) as being anticipated by US 2003/0219745 (Tang et al.). SEQ ID NO:324 of Tang et al was found to encode a polypeptide which is 99.4% identical to SEQ ID NO:2. Applicant respectfully traverses this rejection.

Applicant notes from PAIR that Tang et al., US 2003/0219745, application No. 10/120,988 claims priority to US patent No. 6,743,619, which was filed on January 30, 2001. Filed herewith is a copy of a Declaration under 37 C.F.R. §1.131 with Exhibits A-D. The Declaration presents evidence that the inventor was in possession of the 25466 sequence and identified it as a monocarboxylate transporter before the effective date of Tang et al. Therefore, Tang et al. is not available as prior art under 35 U.S.C. §102(a) and (e). In view of these remarks, Applicant asks that this rejection be withdrawn.

Claims 1, 3-7, 12 and 23-24 were rejected under 35 U.S.C. §102(a) and (e) as being anticipated by US 2004/0024183 (Lee et al.). SEQ ID NO:46 of Lee et al. was found to be 90.3% identical to SEQ ID NO:3 and encodes a polypeptide that is 90.2% identical to SEQ ID NO:2 and comprises at least 120 contiguous amino acids of SEQ ID NO:2. Applicant has amended claims to eliminate sequence variants specifically hybridizing to SEQ ID NO:3 and fragments which comprise at least 120 contiguous amino acids of SEQ ID NO:2. In view of these amendments, Applicant asks that this rejection be withdrawn.

CONCLUSION

The foregoing amendments and remarks are being made to place the Application in condition for allowance. Applicant respectfully requests the timely allowance of the pending claims because, in view of these amendments and remarks, Applicant respectfully submits that the objections to the specification and rejections of the claims under 35 U.S.C. § 101, 112 and 102(a) and (e) are overcome. Applicant believes that this application is now in condition for allowance. Early notice to this effect is solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned. If the Examiner disapproves of Applicant's amendments and remarks in this response, Applicant requests a prompt mailing of a notice to that effect.

This paper is being filed timely as a request for a one month extension is being filed concurrently herewith. No additional extensions of time are required. In the event any

additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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MILLENNIUM PHARMACEUTICALS, INC.

By _____

Tracy M. Sioussat, Ph.D.
Registration No. 50,609
40 Landsdowne Street
Cambridge, MA 02139
Telephone - 617-374-7679
Facsimile - 617-551-8820